Development and Characterization of a New Test System to Challenge Personal Protective Equipment with Virus-Containing Particles

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Objectives

To develop, characterize, and validate an improved test system to challenge personal protective equipment (PPE) with virus-containing particles (VCPs).

Background

- VCPs produced by infected patients talking, coughing, and sneezing span a diversity of sizes and contributes to the spread of some respiratory diseases.¹
- PPE such as filtering facepiece respirators (FFRs) and surgical masks (SMs) are often used by healthcare workers to reduce the spread of respiratory viruses. When used in the presence of an infected patient, PPE can become contaminated with VCPs (fomite) and are typically discarded after each patient-encounter.
- Previous test systems^{2,3} used in PPE reuse, performance, and handling research were limited in their ability to generate diverse particle size ranges and types. There is a need for versatile test systems capable of generating poly-disperse distributions of droplets ("wet" VCPs) and droplet nuclei ("dry" VCPs).

Materials and Methods

 The bio-aerosol respirator testing system (BARTS-II) was used to challenge PPE with VCPs (Fig. 1):



Fig. 1. BARTS consists of an air supply (1A & 1B); HEPA filter (1C); air regulator (1D); Vibrating Orifice Aerosol Generator (VOAG) (2); nebulizer (3); exposure chamber (4); a head form with a FFR (5A); breathing simulator (5B); Aerodynamic Particle Sizer (APS) (6A), Scanning Mobility Particle Sizer (SMPS) (6B), and Spraytec Laser system (6C).

- MS2 virus, plaque assay, and aerosol generator fluid were prepared according to the method of Vo et al.²
- NIOSH-certified N95 and P100 FFRs and SMs were contaminated for 22 minutes using a breathing machine by passing a challenge aerosol generated with conditions designed to generate poly-dispersed distributions of viral droplet nuclei and droplets.

- <u>Droplet nuclei experiments</u>: Nebulizer (12 L/min + 30 L/min dilution air) and VOAG (1 L/min dispersion + 49 L/min dilution air) were used to generate droplet nuclei via evaporation into the exposure chamber (23 °C, 35% RH).
- <u>Droplet experiments</u>: The same nebulizer and VOAG parameters as above, but without dilution air were used to generate droplets into the chamber (25 °C, 90% RH).
- <u>Aerosol characterization</u>: The SMPS, APS, and Spraytec were used to characterize the particle concentration and size distribution at 10 different locations within the chamber.
- FFR contamination assessment: Viable MS2 trapped at different locations (top, center, bottom, left, and right areas; Fig. 2) were measured. Viable MS2 trapped within each FFR layer was also determined by separating each layer and cutting it into 2 cm x 2 cm coupons.
- Filtration efficiency (FE): FE = $[1 - (N_p/N_e)] \times 100$ where N_p = viable MS2 that penetrated the PPE(trapped on the downstream filters, Fig. 2); N_e = total viable MS2 entered onto PPE (MS2

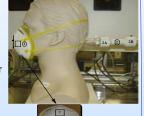


Fig. 2. Head form and downstream collection filter (DCF): test FFR sealed to the headform (1) & sample coupons for the uniform deposition experiment (T, top; C, center; B, bottom, L, left; R, right); DCF holder for the filtration efficiency experiment (2); first DCF in the front filter holder (2A) & second DCF in the back filter holder (2B).

on tested PPE + MS2 on downstream filters).

Results

- Aerosol characterization (near PPE): The size distribution from the droplet nuclei experiments measured at the front of the PPE using the SMPS and APS, ranged from 0.02 to 10.3 μ m, with 96% of particles centered between 0.2–4.0 μ m (Fig. 3). The mass median diameter (MMD) was 0.60 μ m with a geometric standard deviation (GSD) of 1.64 and a mode of 0.96 μ m. The size distribution from the droplet experiments (Fig. 4), measured using the Spraytec, ranged from 0.6 to 100 μ m, with a median [Dv(50)] of 5.03 μ m.
- <u>Aerosol uniformity</u>: The average concentrations of droplet nuclei ranged between 1.72x10⁷–1.82x10⁷ particles/cm³ (n=3), with coefficient of variations (CVs) at different chamber locations ≤ 1.93%. Particle concentrations for the droplet experiments were also found to be uniform throughout the chamber, ranging from 6.39x10⁴ to 6.90x10⁴ particles/cm³.

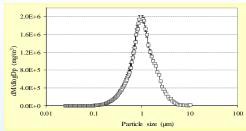


Fig. 3. Size distribution of the aerosol from the droplet nuclei experiments as measured by the SMPS and APS (combined).

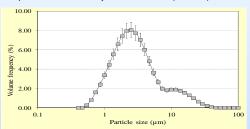


Fig. 4. Size distribution of the aerosol from the droplet experiments as measured by the Spraytec laser diffraction system.

These results indicated that the viral aerosol concentrations and size distributions were relatively uniform throughout the chamber.

- FFR contamination (spatial variation): Viable MS2 from the droplet nuclei experiments trapped at different FFR locations were quantified and found to range from 1.05x10⁵ to 1.14x10⁵ PFU/cm². Viable MS2 from the droplet experiments were also found to range from 1.10x10⁵ to 1.19x10⁵ PFU/cm² at different FFR locations. These results show that the test system could contaminate FFRs with MS2 uniformly under both experimental conditions, meeting ASTM E2720 and E2721 quality requirements^{4,5}.
- <u>FFR contamination (layer by layer variation)</u>: MS2 trapped within each FFR layer was also determined (Table 1).
 More than 97% of the MS2 was found on the outer and middle layers of the N95 FFR models.
- <u>Filtration efficiency</u>: As expected, average FEs were highest for the P100 FFRs (99.91–99.94%), followed by N95 FFRs (96.57–98.18%) and SMs (78.69–80.43%).

Table 1. MS2 trapped within each FFR laver

FFR type	Particle type	Layer (material)	Average MS2 $(PFU/cm^2 \pm STD, n = 3)$	Percen
North N95	Droplets	Layer 1: Outer layer (hydrophobic)	$1.2x10^5 \pm 9.3x10^3$	59%
		Layer 2: Middle-a (hydrophilic + hydrophobic)	$3.7x10^4 \pm 4.0x10^3$	19%
		Layer 3: Middle-b (hydrophobic)	$4.2x10^4 \pm 5.5x10^3$	21%
		Layer 4: Inner layer (hydrophilic)	$2.0x10^3 \pm 3.9x10^2$	1%
	Droplet nuclei	Layer 1: Outer layer	$1.0x10^5 \pm 5.7x10^3$	56%
		Layer 2: Middle-a	$3.4x10^4 \pm 4.6x10^3$	18%
		Layer 3: Middle-b	$4.2x10^4 \pm 6.2x10^3$	23%
		Layer 4: Inner layer	$6.0x10^3 \pm 2.5x10^2$	3%
Gerson N95	Droplets	Outer layer (hydrophilic)	$6.4x10^4 \pm 3.0x10^3$	40%
		Middle layer (hydrophobic)	$9.4x10^4 \pm 4.6x10^3$	59%
		Inner layer (hydrophilic)	$1.2x10^3 \pm 2.9x10^2$	1%
	Droplet nuclei	Outer layer (hydrophilic)	$6.1x10^4 \pm 6.7x10^3$	37%
		Middle layer (hydrophobic)	$1.0x10^5 \pm 3.6x10^3$	61%
		Inner layer (hydrophilic)	$3.2x10^3 \pm 2.6x10^2$	2%

Conclusions

- BARTS-II was capable of (1) producing poly-disperse distributions of viral droplets and droplet nuclei by varying the aerosol generator operating parameters and humidity in the test chamber, (2) uniformly depositing viral droplets and droplet nuclei onto FFR, and (3) measuring FE.
- Viable MS2 deposited on FFR met ASTM E2720-10 and E2721-10 quality requirements.
- BARTS-II could find utility in updating test methods for comparing PPE decontamination methods and for studying the role of PPE and surfaces in fomite transmission.

Disclaimer

The findings and conclusions in this poster have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

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